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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/915,776	07/26/2001	Hyesook Kim	3087.00005	6900

7590 11/19/2003

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EXAMINER

SNEDDEN, SHERIDAN

ART UNIT PAPER NUMBER

1653

DATE MAILED: 11/19/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

<b>Office Action Summary</b>	<b>Application No.</b> 09/915,776	<b>Applicant(s)</b> KIM ET AL.	
	<b>Examiner</b> Sheridan K Snedden	<b>Art Unit</b> 1653	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

**P** **eriod for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☐ Responsive to communication(s) filed on \_\_\_\_.
- 2a) ☒ This action is **FINAL**.                      2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 1-3, 10-13, 15 and 16 is/are pending in the application.
- 4a) Of the above claim(s) none is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-3, 10-13, 15 and 16 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 26 August 2003 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. §§ 119 and 120**

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).  
a) ☐ All   b) ☐ Some \* c) ☐ None of:  
1. ☐ Certified copies of the priority documents have been received.  
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_.  
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).  
\* See the attached detailed Office action for a list of the certified copies not received.
- 13) ☒ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application) since a specific reference was included in the first sentence of the specification or in an Application Data Sheet. 37 CFR 1.78.  
a) ☐ The translation of the foreign language provisional application has been received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121 since a specific reference was included in the first sentence of the specification or in an Application Data Sheet. 37 CFR 1.78.

**Attachment(s)**

- |  |   |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892)                             | 4) <input type="checkbox"/> Interview Summary (PTO-413) Paper No(s). ____.  |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)         | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449) Paper No(s) ____. | 6) <input type="checkbox"/> Other: _____                                    |

## **DETAILED ACTION**

### ***Response to Amendment***

1. Claims 1-3, 10-13, 15 and 16 are currently pending. Applicant's amendment to claims 1, 10, 15 filed 26 August 2003 is acknowledged.

### ***Withdrawal of Objections and Rejections***

2. The objections and/or rejections not explicitly restated or stated below are withdrawn.

### ***Maintained Objections and Rejections***

#### ***Claim Rejections - 35 USC § 102***

3. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1-3 and 15-16 are rejected under 35 U.S.C. 102(b) as being anticipated by Cassina *et al.* Cassina *et al.* teach a method for assessing oxidative stress by measuring nitrated cytochrome c, obtained from an *in vivo* source. On page 21412 (first paragraph and figure 4), Cassina *et al.* teach that increased oxidative stress resulting from higher concentrations of peroxynitrite lead to the dimerization, or covalent polymerization, of nitrated cytochrome c (regarding claim 1-3 and 15-16). Thus, the reference anticipates the claimed invention.

Applicant's arguments filed 26 August 2003, have been fully considered but they are not persuasive. Applicant urges that dimerization does not necessarily from covalent bonds and non-

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covalent types of dimers could exist in the teachings of Cassina *et al.* Additionally, applicant argues that dimer of Cassina *et al.* could be an aggregate. However, Cassina *et al.* at page 21412 teaches nitrated, dimerized cytochrome c. Applicant's arguments provide no factual evidence to the contrary and are thus unpersuasive.

### ***Claim Rejections - 35 USC § 103***

4. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 1-3, 10-13 and 15-16 are rejected under 35 U.S.C. 103(a) as being unpatentable over Cassina *et al.* in view of Ahern (The Scientist, 1995, Vol 9, No: 15, page 20).

Cassina *et al.* teach a method for assessing oxidative stress by measuring nitrated cytochrome c, obtained from an *in vivo* source. On page 21412 (first paragraph and figure 4), Cassina *et al.* teach that increased oxidative stress resulting from higher concentrations of peroxynitrite lead to the dimerization, or covalent polymerization, of nitrated cytochrome c (regarding claim 1-3 and 15-16). As indicated in the method steps producing the results of figure 4, Cassina *et al.* performed SDS-PAGE and western blot analysis to determine the extent of nitration and polymerization (regarding claims 10-13).

Ahern teach the benefits of an assay kit. Ahern teach that providing reagents and method step in a ready made kit allowed scientist to save time and money, especially when conducting standard lab protocols.

Taken together, it would have been obvious to the person of ordinary skill in the art at the time the invention was made to supply the materials and instructions of the method taught by Cassina *et al.* The person of ordinary skill in the art would have been motivated to prepare a kit in order to save time and money. The person of ordinary skill in the art would have expected success in preparing the kit as the steps performed and materials utilized are standard in the art. Thus, the claimed invention was within the ordinary skill in the art to make and use at the time it was made and was as a whole, *prima facie* obvious.

Applicant's arguments filed 26 August 2003, have been fully considered but they are not persuasive. Applicant urges that dimerization does not necessarily from covalent bonds and non-covalent types of dimers could exist in the teachings of Cassina *et al.* Additionally, applicant argues that dimer of Cassina *et al.* could be an aggregate. Finally, applicant argues that there is no suggestion in the prior art for a kit of the method taught by Cassina *et al.*

Applicant's arguments are considered but not found to be persuasive. Cassina *et al.* at page 21412 teaches nitrated, dimerized cytochrome c. Applicant's arguments provide no factual evidence to the contrary and are thus unpersuasive. In addition, Cassina *et al.* provides all the steps and materials necessary for development of a kit as taught by Ahren. Ahren teaches and suggest packaging scientific methods in the form of a kit for commercial use. Thus, the claims are anticipated and obvious.

### ***Conclusion***

5. No claims are allowed.

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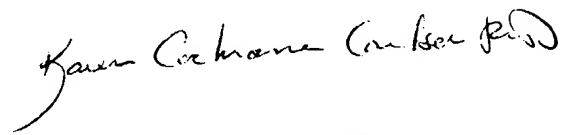
Any inquiry concerning this communication or earlier communications from the examiner should be directed to Sheridan K Snedden whose telephone number is (703) 305-4843. The examiner can normally be reached on Monday - Friday, 8:30 AM to 5:00 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Christopher Low can be reached on (703) 308-2923. The fax phone number for regular communications to the organization where this application or proceeding is assigned is (703) 746-3975.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-0196.

SKS  
November 10, 2003

SKS



KAREN COCHRANE CARLSON, PH.D.  
PRIMARY EXAMINER